

AMENDMENTS TO THE SPECIFICATION:

Please replace paragraph [0005] with the following amended paragraph:

[0005] The expandable osmotic layer of the controlled release liquid capsules taught in the referenced publications typically includes an osmopolymer, such as sodium carboxy methylcellulose (NaCMC), an osmotic agent, such a NaCl, and a film former, such as hydroxyethylcellulose (Natrasel) (NATRASOL®). To coat an intermediate dosage form with an expandable osmotic layer incorporating these constituents, a coating suspension suitable for a spray coating process is typically formulated by mixing the solid constituents included in the expandable osmotic layer into a two solvent system, such as a water and ethanol solvent mixture. Once the coating suspension is formed, the expandable osmotic layer is coated on intermediate dosage forms using, for example, a known spray coating technique. As is well known, spray coating processes generally involve agitating a batch of devices to be coated (in this case, a batch of intermediate dosage forms) while spraying a coating formulation over or around the devices such that, over a period of time, the devices are coated with a material layer of desired thickness. Coating suspensions previously used to coat an expandable osmotic layer included 4.9 wt% NaCMC, 8.1 wt% NaCl, 3.0 wt% Natrasel NATRASOL®, and 84 wt% solvent mixture, such as, for example a mixture of 62.7 wt% water and 21.3 wt% EtOH solvent. The previously used coating suspensions typically produced expandable osmotic coatings including 30.6 wt% NaCMC, 50.6 wt% NaCl, and 18.8 wt% Natrasel NATRASOL®. Although coating suspensions according to the previous formulations generally produce osmotic layers of acceptable quality when the spray coating conditions are closely monitored to ensure a dry coating process, under wet processing conditions, such coating suspensions produce an unacceptably high number of coated devices having expandable osmotic layers that are cracked and, therefore, unsuitable for further processing.

Please replace paragraph [0031] with the following amended paragraph

[0031] In preferred embodiments of the coating suspension of the present invention, the film former is Natrasel NATRASOL®, the osmopolymer is NaCMC, and the osmotic agent is NaCl.

However, the coating suspension of the present invention, is not limited to the use of such materials. For example, the film former included in the coating suspension of the present invention may also be selected from, for example, hydroxypropyl methylcellulose ("HPMC"), methylcellulose ("MC"), polyvinylalcohol-polyethylene glycol graft polymer (Kollicoat® IR), and polyvinyl-pyrrolidone polymers, such as Kellidene® KOLLIDONE® 25, Kellidene® KOLLIDONE® 30, and Kellidene® KOLLIDONE® VA 64. In addition, the '572 Patent, the '280 Patent, and the '036 Application teach further osmopolymers and osmotic agents (also known as "osmotically effective compounds" or "osmagents") that are suitable for use in the coating suspension of the present invention. The contents of each of the '572 Patent, the '280 Patent, and the '036 Application are incorporated herein in their entirety by reference.

Please replace paragraph [0038] with the following amended paragraph:

[0038] Though the expandable osmotic layer of the present invention may be produced by the coating suspension of the present invention using a spray coating process, any suitable composition or process may be used to provide the expandable osmotic layer of the present invention. In one embodiment, the expandable osmotic layer of the present invention includes Natrasol NATRASOL® as the film former, NaCMC as the osmopolymer, and NaCl as the osmotic agent. Like the coating suspension of the present invention, however, the expandable osmotic layer of the present invention is not limited to Natrasol NATRASOL® as the film former, NaCMC as the osmopolymer, or NaCl as the osmotic agent. As is easily appreciated, the film formers, osmopolymers, and osmotic agents suitable for use in the coating suspension of the present invention are also suitable for use in the expandable osmotic coating of the present invention.

Please replace paragraph [0046] with the following amended paragraph:

[0046] The intermediate dosage forms used in each of the batches were prepared by coating #11 oblong gelatin capsules with a barrier layer. The capsules were each filled with a 200mg Guaifenesin liquid active agent formulation and were supplied by Banner Pharmacaps®. A

barrier layer coating solution for the barrier layer was prepared by mixing 97 wt% Kellieat KOLlicoat® SR latex (30% solid) and 3 wt% propylene glycol. The barrier layer coating solution was then sprayed onto the gelatin capsules in a 52" Hi-coater, until a weight gain of about 40 mg per capsule was achieved. Once prepared, the intermediate dosage forms were divided into eight different batches for further processing.

Please replace paragraph [0047] with the following amended paragraph:

[0047] Four different coating suspensions for the application of expandable osmotic layers were prepared. The first coating suspension included 3 wt% Natrasel NATRASOL®, 4.9 wt% NaCMC (sodium carboxymethylcellulose, 7H4F, MW 700,000), and 8.1 wt% NaCl mixed into 62.7 wt% water and 21.3 wt% ethanol. The second coating suspension included 5 wt% Natrasel NATRASOL®, 4.1 wt% NaCMC (sodium carboxymethylcellulose, 7H4F, MW 700,000), and 6.9 wt% NaCl mixed into 62.7 wt% water and 21.3 wt% ethanol. The third coating suspension included 3 wt% Natrasel NATRASOL®, 4.9 wt% NaCMC (sodium carboxymethylcellulose, 7H4F, MW 700,000), and 8.1 wt% NaCl mixed into 65.3 wt% water and 18.7 wt% ethanol. And the fourth coating suspension included 5 wt% Natrasel NATRASOL®, 4.1 wt% NaCMC (sodium carboxymethylcellulose, 7H4F, MW 700,000), and 6.9 wt% NaCl mixed into 65.3 wt% water and 18.7 wt% ethanol. To prepare each of the coating suspensions, the Natrasel NATRASOL® and NaCMC included in each suspension were suspended in the appropriate amount of ethanol in a first container, and, in a second container, the amount of NaCl included in each coating suspension was dissolved in the appropriate amount of water. The coating suspensions were then completed by slowly adding the NaCl solution used in each suspension to the corresponding ethanol suspension with constant mixing.

Please replace paragraph [0050] with the following amended paragraph:

[0050] After each batch of coated intermediate dosage forms was inspected, the devices were then coated with a semipermeable layer. The coating solution used to coat each batch with a semipermeable layer was prepared by dissolving cellulose acetate (CA398-10) and Pluronie

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PLURONIC® F108 (2-methyloxirane) at a ratio of about 4:1 (w/w) in acetone such that a final coating solution containing 4% (w/v) solids was provided. The coating solution was then applied to each batch of devices in a 24" Hi-coater at a rate of about 180g/min, with the final weight gain of semipermeable layer being about 125 mg per device. After coating each batch with a semipermeable layer, the devices, now coated with an expandable osmotic layer and a semipermeable layer, were inspected a second time.